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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,964	11/21/2000	Michael E. O'Donnell	22221/1030 (RU-339 CIP)	2211

7590*

03/13/2002

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,964

Applicant(s)

O'DONNELL ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 49-56, drawn to an isolated DNA molecule encoding a DNA polymerase III enzyme delta subunit, an expression vector and host cell comprising said DNA molecule and a method of expression of said DNA molecule, classified in class 435, subclass 194.
- II. Claims 1, 2, 16-28 and 49-56, drawn to an isolated DNA molecule encoding a DNA polymerase III enzyme delta prime subunit, an expression vector and host cell comprising said DNA molecule and a method of expression of said DNA molecule, classified in class 435, subclass 194
- III. Claims 29, 30 and 31-39, drawn to a DNA polymerase III enzyme delta subunit, classified in class 435, subclass 194.
- IV. Claims 29, 30 and 40-48, drawn to a DNA polymerase III enzyme delta prime subunit, classified in class 435, subclass 194.
- V. Claims 57 and 58-70 drawn to an isolated clamp loader of a DNA polymerase III-type enzyme, classified in class 435, subclass 194.

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Election of Group I above requires that applicants further

elect one of Groups (A)-(D). Election of Group II above requires that applicants further elect one of Groups (E)-(H). Election of Group III above requires that applicants further elect one of Groups (I)-(L). Election of Group IV above requires that applicants further elect one of Groups (M)-(P). Election of Group V above requires that applicants further elect one of Groups (Q)-(T). Therefore, election is required of one of inventions I-VI and one of inventions (A)-(T).

- (A). Claims 4-6 drawn to a DNA molecule from *Aquifex aeolicus*.
- (B). Claims 7-9 drawn to a DNA molecule from *Thermus thermophilus*
- (C). Claims 10-12 drawn to a DNA molecule from *Thermus maritima*.
- (D). Claims 13-15 drawn to a DNA molecule from *Bacillus stearothermophilus*.

- (E). Claims 17-19 drawn to a DNA molecule from *Aquifex aeolicus*.
- (F). Claims 20-22 drawn to a DNA molecule from *Thermus thermophilus*
- (G). Claims 23-25 drawn to a DNA molecule from *Thermus maritima*.
- (H). Claims 26-28 drawn to a DNA molecule from *Bacillus stearothermophilus*.

- (I). Claims 32 and 33 drawn to a DNA polymerase delta subunit from *Aquifex aeolicus*.
- (J). Claims 34 and 35 drawn to a DNA polymerase delta subunit from *Thermus thermophilus*
- (K). Claims 36 and 37 drawn to a DNA polymerase delta subunit from *Thermus maritima*.

- (L). Claims 38 and 39 drawn to a DNA polymerase delta subunit from *Bacillus stearothermophilus*.
- (M). Claims 41 and 42 drawn to a DNA polymerase delta prime subunit from *Aquifex aeolicus*.
- (N). Claims 43 and 44 drawn to a DNA polymerase delta prime subunit from *Thermus thermophilus*
- (O). Claims 45 and 46 drawn to a DNA polymerase delta prime subunit from *Thermus maritima*.
- (P). Claims 47 and 48 drawn to a DNA polymerase delta prime subunit from *Bacillus stearothermophilus*.
- (Q). Claims 65-67 drawn to a clamp loader of a DNA polymerase from *Aquifex aeolicus*.
- (R). Claims 59-61 drawn to a clamp loader of a DNA polymerase from *Thermus thermophilus*
- (S). Claims 62-64 drawn to a clamp loader of a DNA polymerase from *Thermus maritima*.
- (T). Claims 68-70 drawn to a clamp loader of a DNA polymerase from *Bacillus stearothermophilus*.

It is acknowledged that many of the claims are grouped in more than one Group. The claims will be examined to the extent that they read on the elected Group only.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(T) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA molecules encoding the DNA polymerase III delta and delta prime subunits of Groups I and II, and the DNA polymerase III delta and delta prime subunits of Groups III and IV each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA molecules of Groups I and II are comprised of different nucleic acid sequences and the proteins of Groups III and IV are comprised of different amino acid sequences. The DNA has other utility besides encoding protein such as a hybridization probe, and the proteins can be made

synthetically. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the DNA molecule.

Inventions I-II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA molecules encoding the DNA polymerase III delta and delta prime subunits of Groups I and II, and the clamp loader of Group V each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA molecules of Groups I and II are comprised of different nucleic acid sequences and the clamp loader of Group V is comprised of protein subunits that are comprised of amino acid sequences. The DNA has other utility besides encoding protein such as a hybridization probe, and the proteins can be made synthetically.

Inventions V and III-IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the clamp loader of Group V need not comprise the heterologously expressed delta or delta prime subunits but instead can comprise homologously expressed subunits. The subcombination has separate utility such as for the synthesis of antibodies against the different DNA polymerase III subunits.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Richard Hutson", with a horizontal line extending from the end of the signature.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
March 11, 2002